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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,639	09/19/2001	Andrew L. Niles	34506.115	1780

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Intellectual Property Department  
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EXAMINER

CELSA, BENNETT M

ART UNIT

PAPER NUMBER

1639

DATE MAILED: 09/05/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/955,639	NILES ET AL.
	Examiner Bennett Celsa	Art Unit 1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM  
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on \_\_\_\_ .

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-48 is/are pending in the application.

4a) Of the above claim(s) 1-3, 16-27, 38-40, 43 and 48 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_ is/are allowed.

6) Claim(s) 41, 42 and 45 is/are rejected.

7) Claim(s) 4-15, 28-37, 44, 46 and 47 is/are objected to.

8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_ .

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 & 14 .

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_ .

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_ .

**DETAILED ACTION**

***Status of the Claims***

Claims 1-48 are currently pending.

Claims 1-3, 16-27, 38-40, 43 and 48 are withdrawn from consideration as being directed to a nonelected invention.

Claims 4-15, 28-37, 41, 42 and 44-47 are under consideration.

***Election/Restrictions***

Applicant's election, Paper No. 17, with traverse, of Group II (claims 4-15, 28-37, 41, 42 and 44-47) and Applicant's further election of PRNK (seq. Id. 2) as a species, is also acknowledged. The traversal is on the ground(s) that the reasons provided for restriction groups I-III are "conclusory" and that the examiner's assertion of "pharmaceutical" (e.g. in contrast to diagnostic) use fails to provide "the means for, or the feasibility of, using the claimed peptides as pharmaceuticals". These arguments are not found persuasive for the reasons provided in the reasons for restriction e.g. patentably distinct peptides, different searches (including classification) and burdensome search and the pharmaceutical assertion is supported by applicant's own specification (e.g. pages 1-3). Turning to the election of species, applicant argues that searching P4-P3-P2-P1 is not "burdensome". This is not found persuasive for the reasons provided in the office action e.g. burdensome manual/computer bibliographic and sequence searches requires for individual peptides and for various genuses and subgenerics presently claimed (e.g. comprising, NH blocked and/or COOH blocked).

The requirement is still deemed proper and is therefore made FINAL.

The elected species was not found and the search was therefore extended.

***Information Disclosure Statement***

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The information disclosure statement filed April 1, 2002 (paper no. 7) fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. References recited on the PTO-1449 lacking copies have not been considered (as indicated by line through the references).

***Claim Objections***

Claims 14 and 46 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The peptide PANK is not provided as a generic species.

***Allowable Subject Matter***

Claims 4-15, 28-37, 44 and 46-47 are objected to as being dependent upon a rejected base claim or as containing nonelected subject matter (E.g. claim 4 must be rewritten), but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: the prior art of record fails to disclose or suggest the use of N-terminally blocked (e.g. acetylated)/C-terminally fluorogenic tetrapeptides of the sequence P[KR][any amino acid, especially N] [KR] and their use in kits/assays for screening Beta-trypsin activity (e.g. use of aprotinin to inactivate proteases other than Beta-trypsin).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 41, 42 and 45 are rejected under 35 U.S.C. 102(a,b) as being anticipated by Wei et al. WO 98/50579 (11/98).

Wei et al. teach fluorogenic protease substrates and kits (e.g. containers) thereof (e.g. see page 2) which comprise the sequence Val-Pro-Arg-Gly-Lys (e.g. in solution see page 9; and examples and claims) which is within the scope of the presently claimed invention where: P4-P3-P2-P1 is Pro-Arg-Gly-Lys and Pro which at least one "detectable leaving group" (e.g. fluorogenic) bound to P4-P3-P2-P1 (e.g. at the amino and/or carboxyl terminus) via an "amide bond". It is noted that in a compound/composition claim intended use language (e. g. "for analyzing samples for Beta-tryptase activity" ) is not afforded patentable weight.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 703-305-7556. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Bennett Celsa  
Primary Examiner  
Art Unit 1639

A handwritten signature in black ink, appearing to read "Bennett Celsa".

BC  
September 3, 2003